Food and Drug Administration, HHS

avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenylhydrazine reagent (0.5 percent in 2N hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 375 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note "positive" for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and "negative" for xanthan gum if the sample contains less than 1.5 percent of pyruvic acid by weight.

- (e) The additive is used or intended for use in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer in foods for which standards of identity established under section 401 of the Act do not preclude such use.
 - (f) To assure safe use of the additive:
- (1) The label of its container shall bear, in addition to other information required by the Act, the name of the additive and the designation "food grade".
- (2) The label or labeling of the food additive container shall bear adequate directions for use.

Subpart H—Other Specific Usage Additives

§ 172.710 Adjuvants for pesticide use dilutions.

The following surfactants and related adjuvants may be safely added to pesticide use dilutions by a grower or applicant prior to application to the growing crop:

 $n\text{-Alkyl}~(C_8\text{-}C_{18})$ amine acetate, where the alkyl groups $(C_8\text{-}C_{18})$ are derived from coconut oil, as a surfactant in emulsifier blends at levels not in excess of 5 percent by weight of the emulsifier blends that are added to herbicides for application to corn and sorghum.

Di-n-alkyl (C_8 - C_{18}) dimethyl ammonium chloride, where the alkyl groups (C_8 - C_{18}) are derived from coconut oil, as surfactants in emulsifier blends at levels not in excess of 5 percent by weight of emulsifier blends that are added to herbicides for application to corn or sorghum.

Diethanolamide condensate based on a mixture of saturated and unsaturated soybean oil fatty acids (C_{16} - C_{18}) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

Diethanolamide condensate based on stripped coconut fatty acids $(C_{10}\ C_{18})$ as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

 $\alpha\text{-}(p\text{-}Dodecylphenyl)\text{-}omega\text{-}hydroxypoly}$ (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a proplyene tetramer isomer) with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70

Ethylene dichloride.

Polyglyceryl phthalate ester of coconut oil fatty acids.

 α -[p-(1,1,3,3-Tetramethylbutyl) phenyl]-omega-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70

 $\begin{array}{lll} \alpha\text{-}[p\text{-}(1,1,3,3\text{-}Tetramethylbutyl) & phenyl]-\\ \textit{omega-}\text{hydroxypoly}(oxyethylene) & produced\\ \text{by the condensation of 1 mole of } p\text{-}(1,1,3,3\text{-}\\ \text{tetramethylbutyl}) & phenol & \text{with 1 mole of }\\ \text{ethylene oxide.} \end{array}$

Sodium acrylate and acrylamide copolymer with a minimum average molecular weight of 10,000,000 in which 30 percent of the polymer is comprised of acrylate units and 70 percent acrylamide units, for use as a drift control agent in herbicide formulations applied to crops at a level not to exceed 0.5 ounces of the additive per acre.

§ 172.712 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (CAS Reg. No. 107–88–0) may be safely used in food in accordance with the following prescribed conditions:

§ 172.715

- (a) It is prepared by the aldol condensation of acetaldehyde followed by catalytic hydrogenation.
- (b) The food additive shall conform to the identity and specifications listed in the monograph entitled "1,3-Butylene Glycol" in the Food Chemicals Codex, 4th ed. (1996), p. 52, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.
- (c) It is used in the manufacture of sausage casings as a formulation aid as defined in $\S 170.3(0)(14)$ of this chapter and as a processing aid as defined in $\S 170.3(0)(24)$ of this chapter.

[62 FR 26228, May 13, 1997]

§ 172.715 Calcium lignosulfonate.

Calcium lignosulfonate may be safely used in or on food, subject to the provisions of this section.

- (a) Calcium lignosulfonate consists of sulfonated lignin, primarily as calcium and sodium salts.
- (b) It is used in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect when added as a dispersing agent and stabilizer in pesticides for preharvest or postharvest application to bananas.

§ 172.720 Calcium lactobionate.

The food additive calcium lactobionate may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive is the calcium salt of lactobionic acid (4- $(\beta,D-\beta)$ -galactosido)-D-gluconic acid) produced by the oxidation of lactose.
- (b) It is used or intended for use as a firming agent in dry pudding mixes at a level not greater than that required to accomplish the intended effect.

§172.723 Epoxidized soybean oil.

Epoxidized soybean oil may be safely used in accordance with the following prescribed conditions:

- (a) The additive is prepared by reacting soybean oil in toluene with hydrogen peroxide and formic acid.
- (b) It meets the following specifications:
- (1) Epoxidized soybean oil contains oxirane oxygen, between 7.0 and 8.0 percent, as determined by the American Oil Chemists' Society (A.O.C.S.) method Cd 9-57, "Oxirane Oxygen," reapproved 1989, which is incorporated by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826-3489, or may be examined at the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW... suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.
- (2) The maximum iodine value is 3.0, as determined by A.O.C.S. method Cd 1–25, "Iodine Value of Fats and Oils Wijs Method," revised 1993, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.
- (3) The heavy metals (as Pb) content cannot be more than 10 parts per million, as determined by the "Heavy Metals Test," of the "Food Chemicals Codex," 4th ed. (1996), pp. 760-761, Method II (with a 2-gram sample and 20 microgram of lead ion in the control). which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "http://www.nap.edu"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.